IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

REBECA CUTRUZZULA,	)	
	)	Civil Action No. 14-1474
Plaintiff,	)	
	)	United States District Judge
v.	)	Mark R. Hornak
	)	
BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	United States Magistrate Judge
	)	Cynthia Reed Eddy
	)	
Defendant.	)	
	)	

REPORT AND RECOMMENDATION

CYNTHIA REED EDDY, United States Magistrate Judge.

I. RECOMMENDATION

For the reasons set forth below, it is respectfully recommended that the motion to dismiss filed on behalf of Defendant should be DENIED AS MOOT as to Counts II and III, GRANTED as to Counts IV and V, and DENIED as to Counts VII and VIII.

II. REPORT

A. Background

The Complaint in this action was filed on October 29, 2014 [ECF No. 1] and was amended upon leave of court. [ECF No. 18, "Amended Complaint"]. Plaintiff Rebeca Cutruzzula ("Plaintiff") sues Defendants, Bayer Healthcare Pharmaceuticals Inc., Bayer Pharma AG, and Bayer Oy (hereinafter collectively referred to as "Bayer" or "Defendants"), for personal injuries suffered as a proximate result of Plaintiff being prescribed and using the product Mirena® (levonorgestrel-releasing intrauterine system).

The case was referred to this United States Magistrate Judge for pretrial proceedings in accordance with the Magistrate Judges Act, 28 U.S.C. § 636(b)(1) and Rules 72.1.3 and 72.1.4 of the Local Rules for Magistrate Judges.

On December 29, 2014, Defendant Bayer Healthcare Pharmaceuticals, Inc. filed its first Motion to Dismiss for Failure to State a claim with Brief in Support [ECF Nos. 6, 7]. Plaintiff initially filed a Response in Opposition and Notice of Supplemental Authority [ECF Nos. 12, 13] but ultimately, filed a First Amended Complaint [ECF No. 18] on April 9, 2015, rendering the first Motion to Dismiss moot. [ECF No. 19].

Defendant Bayer Healthcare Pharmaceuticals, Inc.[1] thereafter filed the pending Motion to Dismiss for Failure to State a Claim [ECF No. 20], to which plaintiff has responded.

We have jurisdiction pursuant to 28 U.S.C. §§ 1332, 1441, as well as supplemental jurisdiction over common law and state law claims pursuant to 28 U.S.C. § 1367.

1. Allegations in the Complaint

Plaintiff Rebeca Cutruzzula is a resident of Aliquippa (Beaver County), Pennsylvania. [Amended Complaint at ¶ 1]. Defendant Bayer Healthcare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 100 Bayer Boulevard, Whippany (Morris County), New Jersey 07981. [Amended Complaint at ¶ 2]. Defendants are in the business of designing, manufacturing, marketing,

[1] Defendant Bayer Pharma AG is a company domiciled in Germany and is the parent/holding company of Defendant Bayer Healthcare Pharmaceuticals, Inc. [Amended Complaint ¶ 3]; Defendant Bayer Oy is organized and exists under the laws of Finland and is headquartered at Pansiontie 47 20210 Turku, Finland [Amended Complaint ¶ 7]. They do not join the pending motion; the parties have agreed that Bayer Pharma AG and Bayer OY will file one Answer after both Bayer Pharma AGand Bayer OY are properly served through the Hague Convention. The Complaint alleges Defendant Bayer Oy sold Mirena® to Defendant Bayer Healthcare Pharmaceuticals, Inc. until September 1, 2008, at which time Bayer Oy sold Mirena® to Defendant Bayer Pharma AG, which resold Mirena® to Defendant Bayer Healthcare Pharmaceuticals, Inc. [Amended Complaint ¶ 24].

formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing prescription drugs and women's healthcare products, including the intrauterine contraceptive system Mirena®. [Amended Complaint ¶ 14]. Mirena® is an intrauterine system that is inserted by a healthcare practitioner during an office visit. Mirena® is a t-shaped polyethylene frame with asteroid reservoir that releases 20 μg/day of levonorgestrel, a prescription medication used as a contraceptive. [Amended Complaint ¶ 22]. At all relevant times, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device Mirena®. [Amended Complaint ¶ 16].

Plaintiff had the Mirena® IUS inserted into her body for the second time without complication according to the manufacturer's instructions on November 25, 2011 by Dr. Jason Hurt at Magee Womancare Center – Monroeville. [Amended Complaint ¶ 170]. Plaintiff received Defendants' "Patient Information Booklet" when her healthcare provider placed her Mirena®. [Amended Complaint ¶ 171]. Plaintiff and her healthcare providers relied on Defendants' representations regarding Mirena® in its package insert, Patient Information Booklet, or otherwise disseminated by Defendants in deciding to use and prescribe Mirena®. [Amended Complaint ¶¶ 172, 173]. Additionally, Plaintiff received, read and/or watched, and relied upon advertising, including television commercials, Defendants' Mirena® website, additional written materials, and/or radio commercials, produced and/or disseminated by the Defendants when deciding to use Mirena® on or before she made her contraceptive decision in November 2011. [Amended Complaint ¶ 174]. Approximately one year after her Mirena® was placed, among other things, Plaintiff began experiencing frequent episodic headaches, eye

discomfort, and blurry vision. [Amended Complaint ¶ 175]. On November 2, 2012, Plaintiff sought treatment with Dr. Lori Kurutz at Daoud Eye Care. Dr. Kurutz diagnosed Plaintiff with swollen optic nerves, and referred her to a neurologist for evaluation of possible IIH/PTC. [Amended Complaint ¶ 176].

On December 12, 2012, Plaintiff was diagnosed with idiopathic intracranial hypertension ("IIH/PTC") by Dr. Michael Reznik at UPMC Mercy, and started on Propanolol and Diamox. [Amended Complaint ¶ 177]. IIH/PTC is a devastating and potentially permanent brain condition that arises when cerebrospinal fluid ("CSF") in the brain causes increased intracranial pressure in the skull and on a patient's optic nerve, leading to vision problems and in some cases, blindness. [Amended Complaint at ¶ 43-44, 50-51]. On or around June or July of 2014, Plaintiff underwent a lumbar puncture with Dr. Barry Reznick, who measured an elevated opening pressure of 27 cm H2O. [Amended Complaint ¶ 178]. In or about May 2013, Plaintiff had her Mirena removed at Adagio Health Aliquippa, in Aliquippa, PA. [Amended Complaint ¶ 179]. At no time prior to her Mirena removal in May 2013 was Plaintiff or her healthcare providers aware of Mirena's link to her condition. [Amended Complaint ¶ 180]. Plaintiff alleges that her IIH/PTC was caused and/or triggered by her Mirena®, and/or her Mirena® contributed to Plaintiff's development of IIH/PTC. [Amended Complaint ¶ 181]. She alleges that as a result of the injuries she suffered as a result of the defective and unreasonably dangerous Mirena® IUS, she has been permanently injured and has incurred or will incur past and future medical expenses, has experienced or will experience past and future pain and suffering, has incurred or will incur lost wages, and is subject to an increased risk of future harm. [Amended Complaint ¶ 182].

Plaintiff alleges negligence (Count I), design defect (Count II), failure to warn (Count III), breach of implied warranty (Count IV), breach of express warrant (Count V), negligent misrepresentation (Count VI), fraudulent misrepresentation (Count VII), fraud by suppression and concealment (Count VIII).

Defendant's motion is partial; it moves to dismiss the claims involving design defect (Count II), failure to warn (Count III), breach of warranty (Counts IV and V) and fraud (Counts VII and VIII).

2. Standard of Review

Under Rule 12(b)(6), a defendant bears the burden of demonstrating that the Plaintiff has not stated a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6); *see also Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). In *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), the United States Supreme Court recognized that "a Plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 555. The Court emphasized that it would not require a "heightened fact pleading of specifics," but only "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570.

In the subsequent case of *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the United States Supreme Court enunciated two fundamental principles applicable to a court's review of a motion to dismiss for failure to state a claim. First, it noted that "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 678. Thus, although "[Federal] Rule [of Civil Procedure] 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a

prior era . . . it does not unlock the doors of discovery for a Plaintiff armed with nothing more than conclusions." *Id.* at 679-80. Second, the Supreme Court emphasized that "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 679. The task of determining whether a complaint states a plausible claim for relief is "context-specific," and "requires the reviewing court to draw on its judicial experience and common sense." *Id.* The Supreme Court explained:

> The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'"

Id. at 678 (citing *Twombly*, 550 U.S. at 556–57); *see also Fowler v. UPMC Shadyside*, 578 F.3d 203, 210–11 (3d Cir. 2009) (adopting *Iqbal*'s standards).[2]

If a complaint is subject to Rule 12(b)(6) dismissal, a district court must permit a curative amendment unless such an amendment would be inequitable or futile. *See Alston v. Parker*, 363 F.3d 229, 235 (3d Cir. 2004). We must provide the plaintiff with this opportunity even if the plaintiff does not seek leave to amend. *Id.*

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[2] The United States Court of Appeals for the Third Circuit has explicated the *Twombly/Iqbal* standard on several occasions. *See, e.g., Argueta v. U.S. Immigration & Customs Enforcement*, 643 F.3d 60, 70–73 (3d Cir. 2011); *Santiago v. Warminster Twp.*, 629 F.3d 121, 129–30 (3d Cir. 2010); *Fowler* 578 F.3d at 209–211. The Court of Appeals recently summarized the three-step process for analyzing a Rule 12(b)(6) motion:

> To determine whether a complaint meets the pleading standard, our analysis unfolds in three steps. First, we outline the elements a plaintiff must plead to a state a claim for relief. Next, we peel away those allegations that are no more than conclusions and thus not entitled to the assumption of truth. Finally, we look for well-pled factual allegations, assume their veracity, and then "determine whether they plausibly give rise to an entitlement to relief." This last step is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense."

Bistrian v. Levi, 696 F.3d 352, 365 (3d Cir. 2012) (citing *Iqbal* and *Argueta*).

With this standard of review in mind, we now turn to whether the Plaintiff has stated a claim as to those causes of action at issue: Counts II, III, IV, V, VII, and VIII.

B. Discussion

1. Counts II and III

Under Pennsylvania law, products liability claims may not be brought against a pharmaceutical drug company in strict liability. *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888, 889-91 (1996) (applying Restatement (Second) of Torts § 402A cmt. K (1965) to preclude strict liability claims for prescription drugs); *Lance v. Wyeth*, 85 A.3d 434, 451-60 (Pa. 2014) (reaffirming *Hahn*'s bar on strict liability claims but holding that plaintiffs may make claims against pharmaceutical drug companies in negligence for not only manufacturing defects and failure to warn, but also for design defects).

Defendant argues that Plaintiff's design defect and failure to warn claims should be dismissed to the extent that she has pled them under a theory of strict liability. [ECF No. 21 at 4-5]. In response, Plaintiff argues that Defendant's request is moot. [ECF No. 23 at 10]. This Court agrees. As noted *supra*, Plaintiff filed a First Amended Complaint in which she amended certain of her factual and legal allegations, including, *inter alia*, voluntarily removing Plaintiff's strict liability claims in light of *Lance* and *Hahn*. *See* "Plaintiff's Motion for Leave to Amend Her Complaint" (explaining removal of strict liability claims) [ECF No. 16] at 3.

It is therefore respectfully recommended that Defendant's Motion to Dismiss Counts II and III be denied as moot.

2. Count IV and V: Breach of Warranty Claims

Defendant also argues that Plaintiff's breach of warranty claims fail as a matter of law, citing *Hahn* 673 A.2d 888, and other cases which support the broad proposition that the holding

in *Hahn* bars all non-negligence based claims asserted against a manufacturer of prescription drugs [ECF No. 21 at 3], *see Aaron v. Wyeth*, 2010 WL 653984, at *11 (W.D. Pa. Feb. 19, 2010) ("Because *Hahn* requires that this Court dismiss all claims that do not rest on a theory of negligence, Plaintiff's express and implied warranty claims shall be dismissed.")(relying on *Hahn*, 673 A.2d 888); *see also Salvio v. Amgen, Inc.*, 810 F. Supp. 2d 745, 755(W.D. Pa. 2011) (noting that Pennsylvania courts have recognized a "bar" on all "non-negligence based claims asserted against a manufacturer of prescription drugs"); *Leonard v. Taro Pharm.USA, Inc.*, 2010 WL 4961647, at *5 (W.D. Pa. Dec. 2, 2010) (dismissing breach of warranty claims because "Pennsylvania state and federal courts have interpreted *Hahn* broadly to bar all non-negligence based claims asserted against a manufacturer of prescription drugs").

In addition, we note that in *Rowland v. Novartis Pharmaceuticals Corp*., 34 F.Supp.3d 556 (W.D. Pa. 2014) this court held that patients who sued a drug manufacturer could not assert claims for breach of express and implied warranties, citing the same cases as those cited by defendants herein, in addition to *Driesbach v. APP Pharms, LLC*, 2013 WL 5653460, at *2 (M.D. Pa. Oct. 15, 2013) and *Kline v. Pfizer, Inc*., 2008 WL 4787577, at *3 (E.D. Pa. 2008). The weight of this authority favors dismissal of these claims.[3]

It is therefore respectfully recommended that Defendant's motion to dismiss Counts IV and V be granted.

3. Counts VII and VIII

[3] We therefore decline to address the issue of notice under 13 Pa. C.S. § 2607(c)(1).

Next, Defendant argues that Plaintiff's fraud-based claims[4] fail as a matter of law, on the grounds that the claims are rooted in the allegations of failure to warn, which sounds in strict liability as opposed to negligence, citing *Hahn*, 673 A.2d at 889, *Salvio*, 810 F.Supup.2d at 755, *Kester v. Zimmer Holdings, Inc.*, 2010 WL 2696467, at *9 (W.D. Pa. 2010), and *Aaron*, 2010 WL 653984 at *7. Case law in this area is conflicting. In response, Plaintiff cites to *Tatum v. Takeda Pharmaceuticals North America, Inc.*, 2012 WL 5182895 (E.D. Pa. 2012) and *Shelley v. Ethicon*, 2013 WL 3463505, *3 (E.D. Pa. 2013).

In *Tatum* the Court held that fraud claims based on intentional concealment where the seller had knowledge of the risks of prescription drugs and intentionally concealed them are not precluded under *Hahn*. 2012 WL 5182895, * 4. "[T]he court in *Hahn* stated that a seller of prescription drugs must not only warn of risks of which he reasonably should have knowledge, but also warn of risks of which he did, in fact, have knowledge." *Id.* (denying motion to dismiss fraudulent concealment claim against pharmaceutical drug manufacturer). The Court in *Shelley* similarly held that fraud claims concerning prescription medical devices are cognizable if they contain allegations of overt acts that go beyond the mere failure to warn. 2013 WL 3463505, *3 (denying motion to dismiss fraudulent misrepresentation count against manufacturer of implanted surgical mesh for use in repairing ventral hernias).

Accordingly, courts have found fraud claims concerning prescription medical devices cognizable if they contain allegations of "overt acts," such as affirmative misrepresentations,

[4] To establish fraudulent misrepresentation, Plaintiffs must establish "(1) [a] representation (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and, (6) the resulting injury was proximately caused by the reliance." *Chetty Holdings, Inc. v. NorthMarq Capital*, LLC, 2012 WL 1521857, *10 (E.D. Pa. 2012) *citing Ira G. Steffy & Son, Inc. v. Citizens Bank of Pa.*, 7 A.3d 278, 290 (Pa.Super.Ct.2010).

"that go beyond a mere failure to warn." *James v. Stryker Corp*., 2011 WL 292240, at *3-4 (M.D. Pa. Jan. 27, 2011); *see also Tatum,* 2012 WL 5182895, at *4.

Defendant does not argue that the sufficiency of the pleadings bars these claims, but rather focuses on the notion that these allegations should be dismissed because they are not based on a theory of negligence. We note that Plaintiff avers that Defendants made affirmative misrepresentations such as:

> 314. Defendants falsely represented to Plaintiff and Plaintiff's healthcare providers that Mirena® was a safe and effective contraceptive option and/or treatment for heavy menstrual bleeding. The representations by Defendants were in fact false, as Mirena® is not safe and is dangerous to the health of its users
>
> 315. At the time the aforesaid representations were made, Defendants concealed from Plaintiff and her healthcare providers information about the propensity of Mirena® to cause great harm, including the increased risk of developing IIH/PTC, and the increased risk of suffering severe consequences due to not removing Mirena® once a patient experiences symptoms of papilledema and/or IH/PTC.

[Amended Complaint at ¶¶ 314-315].

Plaintiff alleges that Defendants concealed from her and her healthcare providers information about the propensity of Mirena to cause great harm, the nature and/or actions of levonorgestrel, that Mirena causes or contributes to systemic hormonal effects, and affirmatively misrepresented that it is a "low" or "no" hormone contraceptive, that LNG levels are "stable and "without peaks and troughs," and that Mirena causes few to no systemic effects. [Amended Complaint at ¶¶ 370-380, 327-331]. These alleged overt acts and/or affirmative misrepresentations go beyond a mere failure to warn, and case law permits Plaintiff to pursue said claims. By alleging such affirmative misrepresentations on the part of Defendant, Plaintiff

has adequately stated her claims in Counts VII and VIII. It is therefore recommended that Defendant's motion to dismiss said counts be denied.

C. Conclusion

For all these reasons, we recommend that Defendant's Motion to Dismiss [ECF No. 20] be DENIED AS MOOT as to Counts II and III, GRANTED as to Counts IV and V, and DENIED as to Counts VII and VIII. We find that Plaintiff need not be afforded an opportunity to amend her Complaint at Counts IV and V as any amendment would be futile.

In accordance with the Magistrate Judges Act, 28 U.S.C. § 636(b)(1)(B) and (C), and Rule 72.D.2 of the Local Rules for Magistrate Judges, any Objections to this Report and Recommendation are to be filed no later than December 1, 2015. Failure to file Objections will waive the right to appeal. *Brightwell v. Lehman*, 637 F.3d 187, 193 n.7 (3d Cir. 2011). Any party may file Responses to the Objections on or before December 15, 2015.

Dated: November 17, 2015

Respectfully Submitted,
/s/ *Cynthia Reed Eddy*
Cynthia Reed Eddy
United States Magistrate Judge

Cc: Counsel of record via CM-ECF